UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS

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I. INTRODUCTION

Plaintiffs respectfully submit this brief in reply to the Track 1 Defendants' Joint Memorandum in Opposition to Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants. And because some of Defendants' individual briefing addresses common issues such as the proper interpretation of the phrase "Average Wholesale Price" and whether Plaintiffs' liability model is consistent with economic theory (it is),[1] Plaintiffs' reply to those points are included here as well.

The facts are compelling – each of the Track 1 Defendants have been caught red handed publishing artificially inflated AWPs – and have done so to gain market share. To avoid summary judgment, these Defendants now claim that they were allowed to publish AWPs that were fictitious because AWP was never meant by Congress to mean anything. According to Defendants, AWP was a statutory reimbursement mechanism that provided them with Congressional approval to publish fictitious AWPs. And according to Defendants, Class 1 co-payors and Class 2 Medigap insurers are powerless to protect themselves from the foreseeable overpayments flowing from these fictitious numbers.

As Plaintiffs demonstrate below, this is utter nonsense. Indeed, Defendants fail to explain why, if AWP was a meaningless number and if Defendants could publish fictitious numbers, the Lupron defendants plead guilty or why AstraZeneca paid a fine of $355 million.

As we demonstrate below, Plaintiffs are entitled to partial summary judgment as to the meaning of "AWP." And given that meaning, summary judgment as to each Defendant's

[1] The individual briefing regarding common issues to which Plaintiffs respond in part herein are as follows: the entirety of the AstraZeneca brief and certain sections of the BMS (pp. 13-24), J&J (pp. 3-4, 7) and Schering-Plough (pp. 2-6) briefs. And because Plaintiffs are efficiently consolidating their response to these common issues in this single brief, they have taken more than 15 pages. Nonetheless, Plaintiffs are well within the Court's limits for reply briefs supporting summary judgment. For example, Plaintiffs are allotted 30 pages to respond collectively to Defendants' joint brief and the AstraZeneca brief.

deceptive conduct is appropriate because, as demonstrated in the motions directed to each Defendant, there are no material issues of fact regarding each Defendant's (i) role in publishing AWPs, (b) manipulation of AWP and marketing spreads, and (iii) the resulting violation of the relevant consumer protection statutes.

AWP is not a fictitious number and subject to whatever definition Defendants conjure up at the moment. The meaning of AWP can and should be determined by the plain meaning rule and guided by the interpretations of Congress, HFCA/CMS and the OIG, all of which define AWP as a number that means the average price that a retailer pays. In this case, the retailers include physicians who sell directly to members of the Class. Such an interpretation is consistent with Congress' purpose that estimated actual cost ("EAC") would be used to determine the "usual and customary charge." When Congress provided AWP as an alternate reimbursement mechanism, it strains credibility to suggest AWP would also not be grounded in actual and reasonable costs. Such an interpretation is fully supported by OIG and agency interpretation of the meaning of AWP. As Mr. Scully of CMS put it, "the AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies." The OIG has concurred and made it clear that published AWPs must include price reductions, discounts and other similar inducements and that manipulation of AWP is illegal.

If the Court declines to grant summary judgment based on the plain meaning rule, then it should do so only from 1998 forward, when Congress began discounting AWP. However, even in this period, summary judgment is appropriate because as demonstrated below Congress still intended that AWP be reasonably related to actual costs.

Finally, Plaintiffs' interpretation of the meaning of AWP is far more logical than Defendants', who suggest no definition and posit that AWP means essentially nothing, thereby allowing them to publish completely fictitious numbers as a basis for reimbursement.

II. PLAINTIFFS HAVE SUBSTANTIALLY COMPLIED WITH L.R. 56.1

Defendants complain that Plaintiffs have failed to comply with the L.R. 56.1 because Plaintiffs' L.R. 56.1 Statement incorporates by reference record citations from Plaintiffs' memorandum instead of copying them into the L.R. 56.1 Statement itself. This is a shameful exercise in the elevation of form over substance. And it is, as a matter of law, wrong.

Plaintiffs have submitted an L.R. 56.1 Statement containing a list of 77 numbered paragraphs. Every paragraph consists of a simple declarative statement no greater than one sentence in length setting forth a single undisputed fact. Every paragraph is supported by record citations identified in Plaintiffs' accompanying memorandum, including specific deposition transcript citations, document page references, and witness quotations. Every record citation is supported by the source material itself – documents, Defendants' deposition testimony, and affidavits – reproduced in Plaintiffs' Appendix.

Defendants would have the Court believe that Plaintiffs' incorporation by reference of their record citations constitutes a *per se* violation of L.R. 56.1, but in fact there is no "mechanical rule" governing the length, content, or format of an L.R. 56.1 Statement. *Alsina-Ortiz v. Laboy*, 400 F.3d 77, 81 (1st Cir. 2005) (reversing district court's grant of summary judgment for failure to comply with L.R. 56.1 analogue as to one defendant). In evaluating L.R. 56.1 challenges, courts look to whether the substance of the rule is met. *See Dynamic Mach. Works, Inc. v. Machine & Elec. Consultants, Inc.*, 352 F. Supp. 2d 83, 85 n.1 (D. Mass. 2005) (Young, J.) (summary judgment for plaintiff granted despite failure to submit a separate L.R.

56.1 Statement where plaintiff presented a list of numbered facts in its Memorandum and Reply); *Grabowski v. Bank of Boston*, 997 F. Supp. 111, 115 n.2 (D. Mass. 1997) (Saris, J.) (where cross-motions for summary judgment were filed, court disregarded plaintiffs' failure to submit an L.R. 56.1 counterstatement).

Defendants' challenge to the adequacy of Plaintiffs' L.R. 56.1 statement is belied by their own response to it. Each Defendant has submitted an extensive counterstatement, admitting or disputing as the case may be each numbered paragraph applicable to each Defendant. By arguing noncompliance, however, Defendants evade addressing directly the 300-plus exhibits and deposition testimony incorporated by reference from Plaintiffs' memorandum into their L.R. 56.1 statement and fail themselves to satisfy the purposes of L.R. 56.1. *See Swallow v. Fetzer Vineyards*, 46 Fed. Appx. 636, 638-39 (1st Cir. 2002) (describing district court's failure to evaluate facts set forth in filings as a whole as "not useful").

Defendants cite case dicta to support their request that Plaintiffs' L.R. 56.1 Statement should be disregarded, but none of these decisions actually rests on the alleged L.R. 56.1 noncompliance. *See, e.g., Corrada Betances v. Sea-Land Service, Inc.*, 248 F.3d 40, 44 n.2 (1st Cir. 2001) (summary judgment affirmed where L.R. 56.1 counterstatement ***conceded*** key material facts as "incontrovertible"); *Morales v. A.C. Orssleff's EFTF*, 246 F.3d 32 (1st Cir. 2001) (defects in plaintiff's opposition to L.R. 56.1 analogue noted but not considered in summary judgment ruling); *Gosselin v. Webb*, 242 F.3d 412 (1st Cir. 2001) (movants' L.R. 56.1 noncompliance not a factor in court's decision); *Rivera v. Riley*, 209 F.3d 24, 27-28 (1st Cir. 2000) (even where plaintiff failed to make "the slightest effort to comply with this requirement," court evaluated and ruled on the merits); *Moore v. Marty Gilman, Inc.*, 965 F. Supp. 203, 207 n.1 (D. Mass. 1996) (although plaintiffs failed to submit L.R. 56.1 statement, "my recommendation

would be the same based upon my independent review of the entire summary judgment record of the parties"); *Key Trust Co. v. Doherty, Wallace, Pillsbury & Murphy, P.C.*, 811 F. Supp. 733, 734 (D. Mass. 1993) (despite criticizing the "seven pages of discursive text" that constituted the plaintiffs' L.R. 56.1 statement, court analyzed the material facts and ruled on the merits).[2]

Plaintiffs' L.R. 56.1 Statement fully complies with this Court's rule, and Defendants' complaint should be rejected.[3]

III. PLAINTIFFS' INTERPRETATION OF AWP IS CONSISTENT WITH THE PLAIN MEANING RULE AND PROPER AS A MATTER OF LAW

Plaintiffs' opening memorandum carefully traced the history of Medicare's use of the AWP pricing benchmark and demonstrated that Congress intended Medicare Part B reimbursements to reflect actual costs in the marketplace or be at least reasonably related thereto. Bountiful support for this conclusion is found in the plain meaning of the words "average wholesale price" as used by Congress, as well as subsequent interpretations of that meaning by Congress, HCFA/CMS and the HHS Office of the Inspector General ("OIG"). *See* Plfs. Br. at 41-46; Plfs. Mem. in Opp. to Defs. Joint Mtn. for Summ. Judg. at 5-8. From the original amendments to the Social Security Act of 1965, to CMS Administrator Thomas Scully's 2002 testimony, to the 2003 OIG Guidelines, it is clear that the federal government expected

[2] District of Massachusetts courts have ruled based on L.R. 56.1 compliance only where no L.R. 56.1 statement whatsoever was filed, or where none of the party's submissions referenced record support. *See, e.g., Dale v. H.B. Smith Co., Inc.*, 910 F. Supp. 14 (D. Mass 1995) (no statement); *GE Capital Healthcare Fin. Servs. v. Fall River Walk-In Emergency Med. Office, P.C.*, 2004 U.S. Dist. Lexis 75 (D. Mass 2004) (no record support).

[3] Of course, if the Court believes it would be aided by a L.R. 56.1 statement that includes Plaintiffs' record citations rather than incorporates them by reference, Plaintiffs would be pleased to submit such a revised statement. *See Ares-Serono, Inc. v. Organon Int'l B.V.*, 151 F.R.D. 215 (D. Mass. 1993) (where neither an L.R. 56.1 statement nor opposition was submitted, court ordered the parties to file them within two weeks).

manufacturers to include relevant discounts in their AWPs and to otherwise refrain from manipulating AWPs and/or marketing spreads based on those AWPs.

In response, Defendants – as they have done for the entire course of this litigation – once again fail to offer a precise definition of AWP, inferring that AWP means whatever Defendants wanted it to mean at any given point in time, no matter how inflated Defendants' AWPs were. Defendants also assert that the plain meaning rule cannot apply, that Mr. Scully's testimony should be disregarded (at least those portions that are inconvenient for Defendants) and that the OIG Guidelines have no significance. Defendants are wrong on each score.

A. The Plain Meaning Rule Applies and Demonstrates that Congress Intended AWP to Be an Actual Average

As the Court has recognized, from 1992 to 1997 Medicare Part B reimbursement was based on the lesser of EAC or AWP, with Medicare carriers choosing to rely on AWP. *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 70 (D. Mass. 2005) ("*In re AWP*") (citing 42 C.F.R. § 405.517, amended Nov. 2, 1998, Jan. 7, 2004 and Nov. 15, 2004).[4] AWP was not defined in any statute or regulation, but, as the Court noted, "EAC was supposed to be measured through surveys conducted by regional Medicare administrators (termed 'carriers'), who were to determine the usual and customary charge ('U&C') for a geographic area." *Id*. The Court has also recognized that, "[b]ecause the carriers never conducted the surveys of EACs, AWP became the basis for most Medicare reimbursement." *Id*. (citing Rosenthal report at 7).

When Congress leaves terms undefined, "Congress intended the words to have their natural, ordinary and familiar meaning." *United States v. 525 Co.*, 342 F.2d 759, 761 (5th Cir.

[4] On January 1, 1998, reimbursement for single-source drugs was changed to the lesser of (i) the billed charge on the Medicare claim form or (ii) 95% of AWP. *Id*. (citing 42 U.S.C. § 1395u(o), amended Dec. 8, 2003; 42 C.F.R. § 405.517). On January 1, 2004, Congress again modified the reimbursement level, this time adopting 85% of AWP. *Id*. (citing 42 U.S.C. § 1395u(o); 42 C.F.R. § 414.707).

1965) (citing *First Nat'l Bank of Cincinnati v. Flershem*, 290 U.S. 504 (1934)); *see also FDIC v. Meyer*, 510 U.S. 471, 476 (1994). Known as the "plain meaning rule," the Supreme Court "has repeatedly emphasized [its] importance," holding that "if the language of a statute or regulation has a plain and ordinary meaning, courts need look no further and should apply the regulation as it is written." *United States v. Lachman*, 387 F.3d 42, 50-51 (1st Cir. 2004) (quoting *Textron Inc. v. Comm'r*, 336 F.3d 26, 31 (1st Cir. 2003)). "Dictionaries of the English language are a fundamental tool in ascertaining the plain meaning of terms used in statutes and regulations." *Lachman*, 387 F.3d at 51. As Plaintiffs have explained, dictionaries show that "average" has a definite meaning as a mean proportion, and that "wholesale price" refers to the price that a retailer pays in expectation of reselling to its customers at a higher price in order to make a profit. *See* BLACK'S LAW DICTIONARY at 135 and 1597 (6th ed. 1990); AMERICAN HERITAGE DICTIONARY at 144 (2d ed. 1991).

AstraZeneca finds ambiguity in the phrase "AWP," AZ Br. at 4, but there is nothing ambiguous about it. AWP applies to prices charged by wholesalers, not the wholesaler's cost as AstraZeneca advances as a possible yet highly improbably meaning (otherwise, Congress would have said "average wholesale cost").[5] Nor does the statute's silence as to geographic scope or time make it ambiguous. Medicare is a national program, so it is reasonable to assume that, unless specified otherwise, AWP was a reference to national prices. As to time, it is wholly reasonable to take a "prevailing" approach, that is, prices prevailing at any given time or as

[5] Nor do Plaintiffs argue, as AstraZeneca contends, that AWP is equivalent to the manufacturer's ASP. AZ Br. at 3. As explained further in Plaintiffs' Memorandum in Opposition to Track 1 Defendants' Joint Motion for Summary Judgment at 8-9, neither Plaintiffs nor Dr. Hartman have taken the position that Defendants should have reported AWPs equal to the ASP. Indeed, Dr. Hartman's 30% "yardstick" recognizes that AWP and ASP were not in lock-step, yet were intended to have a reasonable relationship to acquisition cost. *See also* Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment, ¶¶ 5-8. *See also* Reply Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Summary Judgment ("Hartman Reply Decl.") at ¶¶ 2, 14-15.

otherwise defined later in regulations. Thus, AstraZeneca fails in its attempt to conjure up so many false ambiguities that, if truly existed, would render the phrase meaningless.

Defendant J&J flounders in an effort to find inconsistency in Plaintiffs' position, J&J Br. at 3-4, yet there is nothing inconsistent with Plaintiffs' assertion that AWP be either a mean proportion and also reasonably related to market prices. Thus, AWP is indeed susceptible to a simple construction, despite J&J's deliberate effort to cloak the issue in confusion. Importantly, and as Plaintiffs explained in their opposition to Defendants' motion for summary judgment at pages 8-9, Dr. Hartman's 30% yardstick is conservative. It gives Defendants "the benefit of the doubt" by recognizing a reasonable divergence between AWP and EAC; J&J and all Defendants should be thankful that the yardstick is so generous.

AstraZeneca's "word game" argument, AZ Br. at 5-6, fares no better. It is impossible to determine exactly what AstraZeneca is arguing here, leading to the observation that it is AstraZeneca, and not Plaintiffs, who are playing a "word game." To the extent that AstraZeneca suggests that physicians cannot be compared for economic purposes to retailers who buy drugs and then "sell" them to patients, AstraZeneca is wrong. Notwithstanding the professionalism with which a physician must dispense patient care, the fact remains that the physician makes a profit on the drug administered. Most physicians purchase those drugs from wholesalers but under contracts with manufacturers[6] and "resell" them to Medicare and Medicare beneficiaries, making the physicians logical retailer surrogates.

AstraZeneca also argues that it would be absurd for Congress, in amending the statute in 1998 to base AWP reimbursements on 95% of AWP, to have intended AWP to be real. AZ Br.

[6] The physician or his or her practice group typically either has a contract directly with a manufacturer or purchases under a GPO contract with a manufacturer.

at 6-7. Yet, as Judge Stearns recognized, it is "likely that by setting the Medicare reimbursement rate below the AWP, Congress took a tentative step towards using Medicare's purchasing power as a means of driving down the cost of prescription drugs to the Medicare program. 'Average,' after all, means that in a competitive market, some prices will be higher and some lower than the median. Congress might reasonably have wished to put Medicare on the lower rung of the equation." *In re Lupron® Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 163 (D. Mass. 2003).

Defendants cite *Lachman* for the proposition that, when a statute uses a technical term of art, it is "defined more appropriately by reference to a particular industry usage than by the usual tools of statutory construction." Defs. Br. at 7 (quoting *Lachman*, 387 F.3d at 53); *see also* AZ Br. at 9 & n.17. While this is indeed an exception to the plain meaning rule, it is ***rarely*** employed. "[C]ourts will only look behind statutory language in the rare case where a literal reading must be shunned because it would produce an absurd outcome." *Textron, Inc. v. Comm'r*, 336 F.3d 26, 31 (1st Cir. 2003) (quoting *Sullivan v. CIA*, 992 F.2d 1249, 1252 (1st Cir. 1993)). It is quite a stretch to find that a real marketplace average "produce[s] an absurd outcome." What is absurd is Defendants' contention that AWP meant the deliberately inflated prices reported by Defendants. Had Congress intended AWP to be divorced from reasonable costs, it surely would have said so explicitly, either in the statute itself or via a clear record of legislative history. Moreover, the disputed term must actually be a technical term of art, *Lachman*, 387 F.3d at 53, yet this is hardly a technical area. Indeed, if the plain meaning rule can apply in such technical and/or sensitive arenas as national security (*Lachman*), the tax code (*Textron*), and the CIA (*Sullivan*), surely it should apply here. Defendants cannot demonstrate that this is just such a "rare case" where the plain meaning rule should be "shunned."

In any event, when looking behind the statutory language, we find that congressional action and subsequent official pronouncements have been consistent with this plain meaning. "In interpreting statutes we must adopt the definition most consistent with the statute's purpose." *Lachman*, 387 F.3d at 51.[7] "We also construe a regulation in light of the congressional objectives of its underlying statute." *Id*. at 52. As the Court has highlighted, although AWP was not defined, "EAC was supposed to be measured through surveys conducted by regional Medicare administrators (termed 'carriers'), who were to determine the usual and customary charge ('U&C') for a geographic area." *In re AWP*, 230 F.R.D. at 70. When Congress provided AWP as an alternative reimbursement basis to EAC, it strains credulity to posit, as Defendants do, that AWP would be divorced from actual and reasonable costs in the marketplace. A much more credible interpretation consistent with the statute's purpose is that AWP would be a national average of costs as a substitute for the regional-centric (and much more difficult to accomplish) EAC surveys. This is also consistent with Meredith Rosenthal's historical assessment of Medicare reimbursement policy, which has always been linked to the "reasonable costs of such services." Rostenthal Tutorial at 6. Again, it is difficult to understand why Congress would establish a reimbursement regime not grounded in reasonable costs.

Furthermore, in 2003, the House Committee on Ways and Means acknowledged that "AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." H.R. Rep. 108-178(II), 108th Cong. (July 15, 2003) at 197 (found at Ex. 82 to Defs. Mem. Supp. Sum. Judg.). Thomas A. Scully, former Administrator of the Centers for Medicare

[7] *See also Holloway v. United States*, 526 U.S. 1, 9 (1999) (noting that "statutory language should be interpreted consonant with 'the provisions of the whole law, and . . . its object and policy'") (quoting *John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 510 U.S. 86, 94-95 (1993)); *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979) ("As in all cases of statutory construction, our task is to interpret the words of these statutes in light of the purposes Congress sought to serve.").

& Medicaid Services ("CMS"), testified to Congress that "AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies."[8] And the OIG Guidelines emphasize the requisite accuracy of Defendants' price reporting for reimbursement purposes: "Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23733-734 (May 5, 2003).

In sum, these historical touchstones and *ex-post* pronouncements all demonstrate that Congress always intended Medicare Part B drug reimbursement to be reasonably related to prevailing costs in the marketplace and not some fictitious, inflated standard.

B. CMS's Controlling Interpretation Is that AWP Was to Be Based on an Actual Average

Defendants selectively cite from the Scully testimony in a vain effort to demonstrate that CMS always intended AWP to be an inflated number. Defs. Br. at 8-9. But Mr. Scully's comments regarding the meaning of AWP, while inconvenient for Defendants, were absolutely clear: "The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies." Berman Decl., Ex. B at 5. Mr. Scully also referenced "numerous legislative efforts … aimed at ensuring that Medicare and its beneficiaries do not pay more than they should for the limited number of prescription drugs

[8] *See* March 14, 2002, Testimony of Thomas A. Scully on Reimbursement & Access to Prescription Drugs under Medicare Part B, Senate Finance Committee, Subcommittee on Health at 5, attached as Exhibit B to the Declaration of Steve W. Berman in Support of Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants (the "Berman Decl.").

that Medicare covers," and recognized that "Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers, are spending far more ***than the 'average' price that we believe the law intended them to pay***." *Id*. at 2-3 (emphasis added).

Stuck with this agency interpretation so utterly at odds with Defendants' unsupported theory that AWP meant whatever they wanted it to mean at any point in time, Defendants turn to classic dissembling in a callow attempt to explain away the import of Mr. Scully's words. For instance, Defendants proclaim that Mr. Scully went to "great lengths" to say that HCFA, CMS and Congress "have known since 1991 that AWP did not represent an 'average price.'" Defs. Br. at 9. Yet no such statement or even inference appears anywhere in the Scully testimony. Moreover, Mr. Scully never stated that the federal government always knew about huge spreads. Rather, he spoke of manufacturers "increasingly" providing discounts, Berman Decl., Ex. B at 5, yet carefully referenced evidence that individual physicians could not obtain substantial discounts, *id*. at 6. And Mr. Scully never stated that the federal government turned a blind eye to AWP manipulation. Rather, he condemned "situation[s] where a manufacturer can, for certain drugs, arbitrarily increase the reported AWP and, in turn, offer physicians a deeper 'discount,'" *id*. at 5, and recounted years of effort to lower the benchmark as more studies revealed the existence of marketplace discounts, *id*. at 6-8. Importantly, Mr. Scully highlighted Congress's considered decision in 2000 that ***more*** study of Medicare drug pricing was needed, as well as Congress's direction to the GAO to carry out those studies. *Id*. at 6-8 (citing to the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")). Indeed, Mr. Scully even referenced those post-2000 GAO reports. *Id*. at 3.

As Mr. Scully also noted, BIPA provided authority for CMS "to address AWP after reviewing the GAO's findings." *Id*. at 8. And that is exactly what Mr. Scully did with his

testimony. Thus, rather than serving as a summary of evidence that the federal government "always knew" that AWP had no reasonable proximity to actual costs in the marketplace, the Scully testimony summarizes the increased focus that CMS and Congress placed in the early 2000s on the AWP reimbursement benchmark, including the OIG studies conducted in the wake of BIPA. *Id*. at 5. This focus ultimately led to the adoption of a different benchmark in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Mr. Scully's comments, coming on the eve of Congress's adoption of the MMA, which altered the reimbursement benchmark from AWP to ASP, was CMS's formal declaration to Congress that reform was needed after – and only after – a more thorough period of study was concluded. *See, e.g., id.* at 1 (referring to the AWP system "seriously flawed" and calling for reform). Nothing in Mr. Scully's testimony condones Defendants' gaming of the AWP system.

Defendants also attempt to minimize the Scully testimony by asserting that it is not a reliable source of regulatory intent. Defs. Br. at 9. However, this is a plain reversal of the position taken in Defendants' own motion for summary judgment, where they argued that the Court should grant deference to not only HCFA's interpretation of its own regulation, but also HCFA's interpretation of the statute. Defs. Mem. Supp. Summ. Judg. at 9 (citing the precise two cases Defendants now cite in arguing that the Court should ***not*** defer to Administrator Scully's interpretation, to wit, *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504 (1994), and *SSM Rehabilitation Inst. v. Shalala*, 68 F.3d 266, 269-71 (8th Cir. 1995)). Defendants' schizoid approach to HCFA's pronouncement is magnified by reference to AstraZeneca's brief, in which it argues that, where a "'statute is silent or ambiguous with respect to a specific issue,' … the agency's interpretation is binding on the courts if it is one of various permissible interpretations" and that "a court may not substitute its own construction of a statutory provision ***for a***

reasonable interpretation made by the administrator of an agency." AstraZeneca Opp. to Sum. Judg. at 11-12 (quoting *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843-44 (1984)) (emphasis added); *see also SSM Rehabilitation*, 68 F.3d at 269 (courts must defer to administrator's interpretation if that interpretation is both linguistically possible and consistent with the purposes of the statute).

In any event, Defendants overlook the fact that Congress itself provided an interpretation consistent with Mr. Scully's when, in 2003, the House Committee on Ways and Means acknowledged that, although undefined by statute, "AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." H.R. Rep. 108-178(II), 108th Cong. (July 15, 2003) at 197 (found at Ex. 82 to Defs. Mem. Supp. Sum. Judg.).

C. The Court Should Also Defer to the OIG Guidelines

Although Defendants cite freely to various OIG reports in ostensible support of Defendants' own arguments, they argue assiduously against application of the OIG Guidelines cited by Plaintiffs, claiming that the OIG has no authority to make or interpret HHS rules, and that, in any event, Defendants contend that Plaintiffs mischaracterize the OIG Guidelines. Defs. Br. at 10-11. Defendants are wrong on both accounts.

Defendants claim that HHS cannot delegate authority to the OIG, Defs. Br. at 10 (citing, among other cases, *Winters Ranch P'ship v. Viadero*, 123 F.3d 327, 334 (5th Cir. 1997)), but that is not at issue here. No prohibited transfer of authority has occurred as contemplated by the quote Defendants cite from *Winters Ranch*. If so, HHS or CMS surely would have objected to the OIG Guidelines. But not only did they not object, the OIG developed the Guidelines ***in consultation with CMS***, as well as DOJ. *See* 68 Fed. Reg. at 23731 ("we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations

and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration)"). Thus, not only do the OIG Guidelines express the official views of the very agency charged with investigating Medicare fraud, the Guidelines assist the implementation of official CMS policy. *See, e.g., Winters Ranch*, 123 F.3d at 334 ("[N]o transfer of function can occur simply because the IG emulates a function normally performed by the agency as part of the OIG's own independent investigation. In order for a transfer of function to occur, the agency would have to relinquish its own performance of that function.").

Furthermore, the OIG Guidelines do not assume CMS's primary operating responsibilities and instead constitute a supplementary enforcement mechanism, just as Congress intended. *See, e.g., United States Nuclear Regulatory Comm'n v. Federal Labor Relations Auth.*, 25 F.3d 229, 233-34 (4th Cir. 1994) (discussing Congress's intent that the OIG be sufficiently independent so that its investigations and audits are unbiased). Indeed, the Guidelines themselves state that they do "not create any ***new*** law or legal obligations." 68 Fed. Reg. at 23733 (emphasis added).

The Inspector General Act provides the OIG with wide discretion to carry out its investigative functions. As the *Winters Ranch* court noted:

> [T]he Act authorizes and enables the IG to make independent decisions as to how and when to investigate the agency's operation of its programs; it does not withdraw any legitimate investigatory technique from the IG's repertoire, and it does not dictate any particular manner in which the IG must deploy or orchestrate the available devices of inquiry.

123 F.3d at 334; *see also id.* at 330 ("Congress conferred very broad audit, investigatory, and subpoena powers on each Inspector General, as an independent and objective unit of the department or agency, to help promote efficiency and prevent fraud, waste, abuse, and

mismanagement in federal government programs[.]"). Those broad powers include rulemaking authority, as even a cursory review of OIG rules reveals. *See* http://oig.hhs.gov/authorities/regulatory.html for a litany of OIG rules. The OIG Guidelines were promulgated, after the required notice and comment period, in order to assist the IG's operation and investigations relating to, among other things, Medicare, and consequently were a valid exercise of OIG oversight.[9] *See also* 68 Fed. Reg. at 23731 ("The purpose of the compliance program guidance it so encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements."). As such, those Guidelines constitute a valid exercise of agency rulemaking and serve as a touchstone for interpreting federal government expectations regarding AWP. And those expectations are clear:

- Pharmaceutical manufacturers are under a ***legal duty*** not to submit "false, fraudulent, or misleading information" where "reimbursement by Medicare and Medicaid … for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, ***directly or indirectly***, and the manufacturer has knowingly … failed to generate or report such information completely and accurately." 68 Fed. Reg. at 23733 (emphasis added).

- "Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." *Id.*[10]

[9] Furthermore, it does not appear that any drug manufacturer has successfully challenged the OIG Guidelines in any court. Nor has any court held that the OIG lacked the power to issue the Guidelines. Defendants' citation to the hearing transcript from *United States v. Mackenzie*, CR-01-10350-DPW (D. Mass. June 24, 2004), Defs. Br. at 11 n.16, adds absolutely nothing. It is an incomplete transcript from a hearing in what appears to be a kickback case against individual physicians. Indeed, interpretation of the meaning of AWP does not appear to even be at issue, and the incomplete excerpts of the transcript provided by Defendants focus solely on the issue of whether the elements of a violation of the anti-kickback statute are the same as the elements of conspiring to defraud. Moreover, the OIG Guidelines are not even mentioned in the transcript. Nor does *Navarro v. Pfizer Corp.*, 261 F.3d 90 (1st Cir. 2001), help Defendants because the regulations at issue in *Navarro* were issued under the ADA by the EEOC, yet the EEOC sought to apply those regulations under an entirely different statute, the FMLA, that delegates regulatory authority not to the EEOC but to the Secretary of Labor. *Id.* at 99. No such issue is presented here, where the OIG Guidelines constitute a permissible exercise of OIG authority to police fraud.

[10] Defendants claim that this passage has nothing to do with reimbursement and relates solely to AMP and Best Price reporting, Defs. Br. at 10-11, but that is emphatically untrue. First, this quotation appears in the section titled

- "If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated." *Id*. at 23737.

- "[I]t is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product." *Id*.

- "The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product." *Id*.

While the "guidance" aspects of the OIG Guidelines are not mandatory – like, for example, the recommendation that manufacturers develop written policies and procedures – the above mandates are far from "voluntary" as Defendants would have the Court believe. For instance, the OIG made clear that "it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product." 68 Fed. Reg. at 23737. There is simply nothing "voluntary" about the duty not to engage in such illegal conduct, which each of the Defendants did. *See also id.* at 23732 ("***In addition to fulfilling its legal duty to avoid submitting false or inaccurate pricing or rebate information to any federal health care program or engaging in illegal marketing activities***, a pharmaceutical manufacturer may gain important additional benefits by voluntarily implementing a compliance program.") (emphasis added).

"Integrity of Data Used to Establish or Determine Government Reimbursement" and immediately after a paragraph that references government reimbursement generally – and Medicare specifically – based in whole or in part on information generated or reported by a manufacturer either directly or indirectly. It is clear that this context is AWP. Second, although the section does reference AMP and Best Price, that reference appears ***after*** the foregoing quotation.

IV. IF IT DID NOT INTEND AWP TO BE AN AVERAGE OF ACTUAL WHOLESALE PRICES, CONGRESS NONETHELESS INTENDED THAT AWP BE RATIONALLY RELATED TO ACTUAL COSTS IN THE MARKETPLACE

If the Court declines to apply the plain meaning rule for any part of the Class Period and instead looks to industry custom and practice as Defendants advocate, it should do so only for the time period after January 1, 1998, when Congress first "discounted" AWP by revising the reimbursement methodology to be the lesser of the billed charge or 95% of AWP. Although, as Judge Stearns has suggested, in setting reimbursement below AWP effective January 1998, Congress was likely taking a "tentative step towards using Medicare's purchasing power as a means of driving down the cost of prescription drugs to the Medicare program," *Lupron*®, 295 F. Supp. 2d at 163, Defendants argue that Congress so acted in response to emerging studies indicating that drugs were available at discounts off of AWP. Defs. Br. at 6; AZ Br. at 7-8. Even assuming for the sake of argument that Defendants are correct, the government nonetheless expected AWP to be rationally related to actual costs in the marketplace. Defendants can marshal no evidence demonstrating an alternative conclusion.

A. Ad Hoc "Studies" Do Not Alter Congress's Original Intent that AWP Be Grounded in Real Prices in the Marketplace

In a regurgitation of their own motion for summary judgment, Defendants make much of various studies from the 1990s and 2000s indicating that at least some drugs were available at discounts, sometimes significant, off of AWP. But as detailed in Plaintiffs' Memorandum in Opposition to Track 1 Defendants' Joint Motion for Summary Judgment at pages 6-8 and 10-19, the reports and studies cited by Defendants do not alter the conclusion that AWPs were to be within some reasonable zone of actual averages.

The few early reports relied upon by Defendants underscore the government's intent that AWPs be reasonably linked to actual costs. For example, the July 31, 1975 Federal Register report observed that "actual acquisition cost is difficult to determine" and acknowledged comments recommending that "actual acquisition cost" be defined as the published AWP. Defs. Ex. 3 at 32293. Five years later in 1980, the Comptroller General of the United States reported that "programs using EAC (estimated acquisition cost) ***established prices that are very similar to the Average Wholesale Price***." Defs. Ex. 4 at 111 (emphasis added).[11]

Later reports and regulatory actions from the 1990s do not change this conclusion. Defendants argue that HCFA's proposed 1991 regulation demonstrates that AWP was never intended to have any proximity to actual costs. Defs. Br. at 7. But further scrutiny of the proposed regulation demonstrates otherwise. First and most importantly, the proposed regulation explicitly states that "***Medicare policy, since the beginning of the Medicare program, has been to base payment for 'incident to' drugs on the estimated acquisition costs***." Fowler Decl. Ex. 19 at 25 (emphasis added). So much for Defendants' contention that AWP was intended to be divorced from actual costs. Second, although the proposed regulation recognized that some drugs could be acquired at an average discount of 15.9 percent off the published AWP, HCFA was referring to drugs dispensed from pharmacies and not physician-administered drugs, for which HCFA admitted it had no data. *Id*. at 25-26. Indeed, in the following year, HCFA stated

[11] The report also noted that a comparison of AWPs to IMS data tended to "contradict HHS's view that the AWP exceeded the price at which the pharmacist could obtain drugs by 15 to 19 percent." *Id.* at 34. Moreover, the 70th percentile of the IMS data was equal to AWP. *Id.*

that it "lack[ed] assurance that a substantial number of physicians can obtain drugs at the lowest price available." Fowler Decl. Ex. 26 at 12-13.[12]

Turning to the House Report accompanying the Balanced Budget Act of 1997, which acknowledged that AWP ***can*** exceed acquisition costs, this does ***not*** mean that Congress had originally intended AWP to always exceed acquisition costs, that the gargantuan spreads challenged in this lawsuit were acceptable, or that AWP was to have no reasonable relationship to acquisition costs. Nor do Congressional reports from the early 2000s constitute "proof" that Congress never intended AWP to relate to costs. Although some House Reports observed that AWPs did not reflect discounts, Defendants overlook the House Committee on Ways and Means explanation that "AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." H.R. Rep. 108-178(II), 108th Cong. (July 15, 2003) at 197 (Defs. Ex. 82). Defendants also overlook the 2003 MedPAC report, which found that third-party payers were reimbursing for physician-administered drugs on average at 97.5% of AWP with the overall range being 85% to 115% of AWP. Medicare Payment Advisory Commission, *Report to Congress: Variation and Innovation in Medicare*, Table 9-2 (June 2003).

Moreover, in noting that discounts were often but not always reflected in AWP, when passing the MMA in 2003, Congress was reporting on what the AWP system ***had become*** as a result of Defendants' manipulations, and thereby underscoring the need to change the Medicare Part B reimbursement benchmark from AWP to ASP. In no way can these statements logically be interpreted as Congress's retroactive intent that AWP never have any grounding in real costs.

[12] Defendants' citation to Exhibit 40 also does not help them. First, it is an incomplete exhibit, and one cannot determine who was testifying. Second, the material reflects a question and answer session in a Committee Hearing, and does not constitute a statement by the Senate Finance Committee or official legislative history.

Far from demonstrating that Congress, HCFA and CMS never intended AWPs to be reasonably related to actual costs, the evidence reveals that reliable information about true margins was simply not available or understood. Indeed, Congress's enactment of BIPA in 2000 demonstrates that Congress had insufficient information about average drug prices because it commissioned the Comptroller General to study "the average prices at which … drugs … are acquired by physicians and other suppliers…." Defs. Ex. 70 at § 429(a). Had Congress been well aware of pervasive and substantial discounts on physician-administered drugs, it would not have needed to direct the Comptroller to study the issue. And as Dr. Hartman has explained, for most of the Class Period there was confusion regarding true prices in the marketplace for physician-administered drugs:

> While hindsight, illuminated through discovery in this litigation and other litigation, . . . demonstrates that the substantial spreads found with generic self-administered drugs in the late 1990s were indeed reflected in spreads for physician-administered drugs, ***such a general understanding simply did not exist at that time***. No consistent survey information supported such an understanding. Anecdotal information for individual Part B drugs were not sufficient to change the overall expectation throughout the 1990s that the AWP provided ***a reasonable expectation*** for the EAC of Part B drugs.

Hartman Reb. Decl., Part II.C., ¶ 9(g) (footnote omitted) (emphasis added).

As Plaintiffs explained in their opposition to Defendants' motions for summary judgment, a more intensive period of study unfolded in the wake of BIPA, congressional and DOJ investigations beginning in 2000, and the filing of these consolidated lawsuits beginning in 2001. Thus, Congress and HCFA repeatedly recognized that, until 2003, they had incomplete data regarding the actual costs of physician-administered drugs covered by Medicare Part B and consequently could not conclude that actual costs in the marketplace were regularly and substantially below AWP. But once they reached that conclusion in the wake of the OIG studies

that Congress called for in the 2000 BIPA legislation, Congress acted in 2003 to change the benchmark effective 2005 from AWP to ASP and, in 2004 as an interim measure, to lower reimbursement to 85% of AWP.

None of this changes the government's original intent that AWP be linked to actual acquisition costs, as reflected in numerous statements, including the 1991 proposed HCFA regulation quoted above, Administrator Scully's testimony, the 2003 House Report and the OIG Guidelines, which were all highlighted in the prior section. When taken as a whole, the litany of reports that Defendants reference, coupled with congressional actions in reducing reimbursement rates from AWP to 95% of AWP, then to 85% of AWP and then to ASP, do no more than demonstrate that Congress was calibrating the reimbursement benchmark commensurate with data showing that EACs for some drugs were falling relative to AWPs.

Finally, the evidence demonstrates that, until very recently, no one knew about Defendants' concealed efforts to manipulate and market spreads. Not a single report or study cited by Defendants gave an approximation of the true spreads or Defendants' unlawful marketing practices that created the spreads. *See, e.g.*, Plaintiffs' Memorandum in Opposition to Track 1 Defendants' Joint Motion for Summary Judgment at 14-15 (providing examples of huge spreads disclosed only after discovery in this litigation). And not a single document referenced by Defendants demonstrates that Defendants – the only entities armed with full knowledge of the full extent of AWP gaming – took any action to disclose their confidential pricing or their nefarious manipulation and marketing activities.

B. What Do Defendants Believe Congress Expected Reported AWPs to Be?

Defendants claim that there is no plain meaning for AWP and that the Court must look only to "what was published" and nothing more. AZ Br. at 8-9. Assuming that this is a correct

interpretation (and it is not), Defendants leave a myriad of important questions unanswered. What do Defendants believe were HCFA's and CMS's general expectations regarding the relationship between the AWP that was published and EAC? Is it really reasonable to assume that Congress would choose a published reimbursement benchmark that it knew would not constitute a reliable signal for underlying prices in the marketplace? While, according to Defendants, HCFA and CMS knew that AWP exceeded EAC by some amount, did HCFA and CMS ***generally expect*** that the published AWP was a reasonable enough signal for the EAC to continue to rely upon it generally for reimbursement? If so, at what point does the signal become unreasonable? Of course, Defendants have for over four years failed to answer these critical questions because they cannot without conceding that Congress, if it did not intend the plain meaning of AWP to apply, did intend the published AWP to have at least some reasonable proximity to actual costs such that it would serve as a reliable signal.

To the extent that the AWPs for some drugs and, in particular, those at issue in this litigation, have become so far removed from EAC that it cannot be said that any reasonable relationship between the two exists, this has occurred ***because of Defendants' AWP manipulation***. If AWP truly has no meaning, then that is so precisely because Defendants have engaged in the AWP inflation scheme. In other words, Defendants point to the results of their illegal behavior and assert that they cannot be found liable since their illegal behavior has sufficiently eliminated the price relationship in the market, the relationship that had been the basis for industry wide reimbursement practices and procedures in the early 1990s. It is awfully difficult to conclude that this was Congress's or CMS's intent in relying upon AWP as a reimbursement metric. Defendants have a lot of explaining to do, and they have failed to do so for four years.

V. BMS'S CONTENTION THAT "PLAINTIFFS' THEORY DOES NOT MAKE SENSE" IS IRRATIONAL

Closing its brief with a scattershot of baseless assertions, BMS contends that Plaintiffs' theory "does not make sense." BMS Br. at 22-23. But the irrationality lies with BMS's contention and not Plaintiffs' cogent liability theory.

BMS first mischaracterizes Plaintiffs' theory by equating AWP with ASP, something that Plaintiffs have never advocated. Indeed, Dr. Hartman has repeatedly explained that the marketplace has expected that AWP be larger than ASP by a reasonably predictable amount. *See, e.g.*, Sept. 3, 2004 Hartman Declaration, ¶ 10(b); Dec. 15, 2005 Hartman Declaration, ¶¶ 57-59; Hartman Reply Decl., ¶¶ 12-15. From this false premise, BMS then argues that Plaintiffs' theory is "totally at odds with economic concepts and industry practices" and would upset some ephemeral "balance between the goal of providing cost effective healthcare for millions of Americans and providing adequate compensation for providers such as oncologists." BMS Br. at 23. BMS makes no effort to support this statement with expert opinion, historical analysis or indeed any evidence, and, for these reasons alone, the Court should reject it. To the extent that BMS is suggesting that profits on drugs subsidize other provider services, BMS again advances no supporting evidence. Moreover, as Dr. Hartman has explained, to the extent that BMS's and the other Defendants' AWP inflation overstated one of the components of the physician's service – that is, provision of the drug – the overall reimbursement for the bundle of goods and services was inflated. *See, e.g.*, Dec. 16, 2004 Hartman Rebuttal Declaration, ¶¶ 71-73; Hartman Reply Decl., ¶¶ 16-21.

BMS next contends that, had Defendants reported truthful AWPs, higher, not lower, prices would have resulted because manufacturers would have no incentive to offer discounts.

BMS Br. at 23. Not only does this argument lack any citation to expert opinion, it borders on the frivolous. Dr. Hartman opines that this assertion is "junk science." Hartman Reply Decl. ¶ 23. Nothing in this market or any analogous market characterized by high research and development costs suggests that competition among manufacturers would raise their prices or eliminate the incentive for manufacturers to discount their products. The drug manufacturers currently compete aggressively on price, and they would do so in the but-for world for at least the following three reasons. First, competition currently exists to discover and bring to market new single-source physician-administered drugs, which launch at spreads less than 30%, since these drugs compete on clinical profiles. Hartman Reply Decl. ¶ 25.

Second, therapeutic competitors to previously unique single-source drugs have certainly been willing to compete on price at launch, and the incumbent single-source manufacturers have certainly been willing to meet that price competition. They already do so in order to compete on spread.[13] Hartman Reply Decl. ¶ 26. If spread competition were not available to them, they would still compete on price, as do competitors in all other markets, including those involving products with equally complex R&D requirements. *Id*. Normal price competition turns into spread competition in this market because of the historical lack of any transparency between the basis for reimbursement (list price = AWP) and competitive ASPs,[14] although sufficient

[13] *See* ¶ 59 and Attachment F of Dr. Hartman's December 15, 2005 Declaration on Liability and Calculation of Damages. *See also* the Liability Declaration of Professor Meredith Rosenthal.

[14] As Dr. Hartman has explained:

> In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, manufacturers compete to increase their market share. This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers. Although the manufacturer's profit per dose will not increase with the rise in the listed price, the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor. At the same time, coinsurance payments charged to

information is finally accumulating in the wake of the MMA to force providers to pass along manufacturer price competition. *Id.*

Third, generic competitors compete very aggressively on price, and the incumbent single-source manufacturers have been willing to meet that price competition. If spread competition were not available to them, they would still compete on price. *Id*. at ¶ 27.

Manufacturer price reductions are not reflected in AWPs because they understand the non-transparency that exists with reimbursement and strategically respond to take advantage of this opaqueness. If greater transparency existed, and if consumers/payors therefore better understood the spreads and could respond to them, and if manufacturers therefore would not benefit from inflated AWPs, they would lower the AWPs with the ASPs, competing on price at wholesale and at the consumer level. *Id*. at ¶ 28. The Court should roundly reject BMS's irrational and unsupported contentions to the contrary.

VI. J&J'S ARGUMENT THAT "NO LINE CAN BE DRAWN" BETWEEN LAWFUL AND UNLAWFUL CONDUCT IN THIS MARKET, IF VALID, WOULD MEAN THAT NO SPREAD COULD EVER BE UNLAWFUL

J&J argues that it is "absurd" for liability to attach for spreads that exceed 30% but not for spreads that are 29% or less. J&J Br. at 8-9. But what J&J is really saying is that no line can be drawn anywhere – that spreads of 29%, 30%, 500%, 1000% or more ***are per se never unlawful***. J&J's proposition is absurd and ignores well-established principles of competition law which recognize that a line between lawful and unlawful pricing always exists.

> beneficiaries will rise as the AWP increases. . . . Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy. They leave the AWPs at existing levels, and offer larger discounts directly to physicians who choose their drugs over products offered by competitors. In this case, the manufacturers' profit per unit dose will be less, but overall profits increase if the discounts result in increased market share. [Dec. 15, 2005 Hartman Decl., ¶ 53(a).]

Just one example is provided by the Federal Trade Commission *Horizontal Merger Guidelines*, which apply a hypothetical monopolist test that asks whether a 5% price increase for a non-transitory period of time (one year) is profitable for a hypothetical monopolist. If the answer is "yes," then the products assumed for that monopolist constitute an antitrust market. If "no," the market is deemed larger, and the hypothetical monopolist test is applied again, until the product/geographical market is defined. Hartman Reply Decl. ¶ 29.

The point is that the 5% and one year metrics are bright line tests. Could the FTC have chosen 6% and 9 months instead? Possibly. But thresholds must be set, and the *Merger Guidelines* thresholds are not considered absurd, either as a matter of policy or economics. Neither is Dr. Hartman's 30% yardstick, which provides an exhaustively researched and accurate "line in the sand" for market expectations of reasonable spreads on single-source physician-administered drugs. And it bears repeating that the benchmark is conservative. As Judge Stearns remarked, if relatively small spreads were at issue, there almost certainly would not have been criminal prosecutions followed by civil suits. Indeed, the spreads at issue here are far from small, with spreads as great as 130% or more on AstraZeneca's Zoladex; over 687% and 285% on BMS's Vepesid and Cytoxan, respectively; and more than 1535% on Schering's Albuterol. This case is not about "shades of grey."

VII. SCHERING-PLOUGH'S CONTENTION THAT PLAINTIFFS HAVE CHANGED THEIR THEORY IS WRONG

Schering-Plough and Warrick ("SPW") claim that Plaintiffs have changed their theory from their original position that AWPs should have been more closely related to actual costs paid by physicians to one in which AWPs should have been more closely related to manufacturer's costs. SPW Br. at 2-5. SPW misconstrues Plaintiffs' theory.

In Dr. Hartman's damage analysis, he took SPW data and calculated ***manufacturer prices*** to providers by accounting for gross invoice amounts and all price offsets ***to providers only***. Hartman Reply Decl. ¶¶ 37-42. He did so by identifying and netting out any related chargebacks to wholesalers paid by SPW that were related to physician-administered drugs, thereby taking into account the important differences between wholesale prices and contract prices to providers. Dr. Hartman also identified all other price offsets offered to providers. Since a substantial portion of Part B drugs are sold directly to providers, many of the price offsets to intermediaries are not relevant for physician-administered drugs. He labeled this final calculation as the ***manufacturer price*** (ASP). However, Dr. Hartman made it clear that it was the manufacturer price ***to providers***, which is their ***acquisition cost.*** Thus, all price offsets documented in the SPW accounting/invoice data, for which Plaintiffs were given appropriate interpretive information, have been accounted for. To the extent that there are some wholesaler mark-ups on that small portion of Part B drugs that may be distributed through wholesalers not reflected in SPW invoice data, those mark-ups are known to be paper thin and *de minimis* for the purposes here. *Id.*

Hence, there is no "sleight-of-hand" on Plaintiffs' part, as SPW contends; there simply is no contradiction between Plaintiffs' views that (i) AWPs should have been more closely related than they were to actual costs paid by physicians, and (ii) the manufacturer's price. If there is any "sleight-of-hand," it is SPW's unsupported attempt to suggest that there is some difference between (or change in) Plaintiffs' original theories of liability and Dr. Hartman's implementation of the damage calculation. *Id.* at ¶ 40.

VIII. CONCLUSION

For the foregoing reasons, as well as those set forth in Plaintiffs' opening memorandum in support of partial summary judgment, partial summary judgment should be granted against all five Track 1 Defendants.

DATED: April 28, 2006.

By **/s/ Steve W. Berman**

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE
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I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on April 28, 2006, I caused copies of **PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
Steve W. Berman